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09/763,666	05/25/2001	Stephen R. Ash	11020-55	8586

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EXAMINER

NGUYEN, CAMTU TRAN

ART UNIT PAPER NUMBER

3743

DATE MAILED: 02/04/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/763,666

Applicant(s)

ASH, STEPHEN R.

Examiner

Camtu T. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-25 and 44-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-13,16-25 and 44-64 is/are rejected.
- 7) ☒ Claim(s) 14 and 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

This Office Action is in response to applicant's amendment filed on December 8, 2003. Claims 1 and 4 have been amended. Claims 2, 3, and 26-43 have been cancelled. Claims 44-64 are newly added claims. The indication of allowability of claims 3-5 and 7-25 in the previous action has been regrettably withdrawn. The claims, as amended, have been carefully considered and are rejected in the following manner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 57 recites the limitation "said adding" in line 8 of claim 57. There is insufficient antecedent basis for this limitation in the claim. Dependent claims 58-62 depending from claim 57 are inherently rejected under 2nd paragraph of 35 U.S.C 112.

Claim 8 recites the limitation "said adding" in line 2 of claim 8. There is insufficient antecedent basis for this limitation in the claim.

Claim 50 recites the limitation "said adding" in line 2 of claim 50. There is insufficient antecedent basis for this limitation in the claim.

In view of 2nd Paragraph of U.S.C. 112 above, these claims are further rejected as best can be understood and interpreted.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-6, 44-48, are rejected under 35 U.S.C. 102(b) as being anticipated by Sodemann (U.S. Patent No. 6,166,007). Sodemann discloses an antimicrobial lock and a method of inhibiting or preventing infection and blood coagulation in or near a medical prosthetic device after the device has been inserted in a patient comprising administering to the device a pharmaceutically effective amount of a composition comprising an antimicrobial taurinamide derivative that are combined with a biologically acceptable acid or a biologically accepted salt thereof so as to produce a pH into a range from 4.5 to about 6.5 (column 11 lines 28-40, column 15 lines 50-64). Sodemann discloses the acid and/or salt will be used in a concentration effective to bring about the desired anticoagulation effort and such typical concentration of trisodium citrate in the range of 5 to 50 grams per liter (column 12 lines 24-43). Sodemann further discloses polyols can also be used to maintain relatively high concentrations of taurolidine and or taurultam in aqueous solution, such as glycerol (column 10 lines 16-25).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-13, 17, 18, 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sodemann (U.S. Patent No. 6,166,077) in view of Maginot et al (U.S. Patent No. 6,190,371). Sodemann discloses an antimicrobial lock and a method of inhibiting or preventing infection and blood coagulation in or near a medical prosthetic device after the device has been inserted in a patient comprising elements and steps set forth in these claims including a device that must remain in place over protracted periods of time. Sodemann teaches a catheter used in conjunction with a hemodialysis access system for access to a human or animal's vascular system for exchanging of blood between the vascular system and an external processing apparatus are well known in the art. However, Sodemann does not seem to teach the catheter used during a hemodialysis procedure containing the lock solution being maintained in the lumen for a desired amount of time of at least 8 hours. Maginot et al disclose catheters for use in a body of a patient and an associated method of which maintains fluid flow in the catheter system comprising a catheterization that requires a patient undergoes hemodialysis. Maginot et al discloses a "permanent catheterization technique" which is a technique in which the catheter is left in a blood vessel for a relatively long period of time such as months. Therefore it would have been obvious to one skill in the art to utilize the Sodemann device in Maginot et al's permanent catheterization technique as such would maintain the lock solution in the lumen for more at least about 8 hours for the purpose of providing a ready means for vascular access into the patient's bloodstream.

Claim 7, 16, 49, 51-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sodemann (U.S. Patent No. 6,166,077). Sodemann discloses an antimicrobial lock and a method

of inhibiting or preventing infection and blood coagulation in or near a medical prosthetic device after the device has been inserted in a patient comprising elements and steps set forth in these claims. With regards to the amount of lock solution infused into lumen of the catheter, sufficient to fill about 80% to 100% of the internal volume of the lumen, there is nothing unusual, nothing unobvious with this preferred amount. In fact, it would have been obvious to one skilled in the art fill only about 80% to about 100% of the internal volume of the catheter's lumen for the purposes of directing residual blood from remaining in the catheter's lumen, thereby, preventing formation of thrombus through the lumen and as well as of preventing air from entering the blood vessel.

Claims 57-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sodemann (U.S. Patent No. 6,166,077). Sodemann discloses an antimicrobial lock and a method of inhibiting or preventing infection and blood coagulation in or near a medical prosthetic device after the device has been inserted in a patient comprising elements and steps set forth in these claims. With regards to the amount of lock solution infused into lumen of the catheter with an amount of 110% of the internal volume of the lumen, there is nothing unusual, nothing unobvious with this preferred amount. In fact, it would have been obvious to one skilled in the art to fill more than 100% of the internal volume of the lumen to ensure all of the residual blood remaining in the catheter's lumen is expelled to prevent any potential formation of thrombus through the lumen. Applicant discloses in the specification, on page 18 lines 8-14, the recited amount of lock can be injected into the lumen without adverse effects on the clotting system of the patient.

Claims 19-25 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sodemann (U.S. Patent No. 6,166,077). Sodemann discloses an antimicrobial lock and a method of inhibiting or preventing infection and blood coagulation in or near a medical prosthetic device after the device has been inserted in a patient comprising elements and steps set forth in these claims. With regards percentage of bactericidal component weight based on the weight of the bactericidal component, of a citrate salt, it would have been obvious to one skilled in the art to apply such percentage according in order to accommodate a particular application. Applicant does not disclose any criticality for the claimed percentage (specification page 17 lines 12-22).

Claims 5, 13, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sodemann (U.S. Patent No. 6,166,077). Sodemann discloses an antimicrobial lock and a method of inhibiting or preventing infection and blood coagulation in or near a medical prosthetic device after the device has been inserted in a patient comprising elements and steps set forth in these claims including compositions of the present invention can also contain other dissolved additives that can favorably influence their physical properties (column 10 lines 64-67, column 11 lines 1-4). Therefore, it would have been obvious one skilled in the art to also expect polygeline as one of the physical properties influences.

Claims 5, 13, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sodemann (U.S. Patent No. 6,166,077) in view of Satoh et al (U.S. Patent No. 5,109,025). Sodemann discloses an antimicrobial lock and a method of inhibiting or preventing infection and blood coagulation in or near a medical prosthetic device after the device has been inserted in a patient comprising elements and steps set forth in these claims. Satoh et al discloses polyethylene glycol and glycerol as non-toxic additives which can be used with a therapeutic

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agent (column 3 lines 24-51) to treat acute nephritis caused by bacterial or viral infectins.

Therefore it would have been obvious to one skilled in the art to use the additives taught by Satoh et al in Sodemann's lock solution.

Allowable Subject Matter

Claims 14 and 15 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

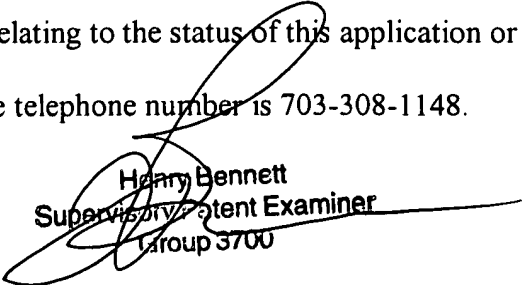
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Camtu T. Nguyen whose telephone number is 703-305-0537. The examiner can normally be reached on (M-F) 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

Camtu Nguyen
January 29, 2004


Henry A. Bennett
Supervisory Patent Examiner
Group 3700